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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,147	09/30/2003	Gilbert R. Gonzales	XANO / 36	5607
26875	7590	12/01/2005	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			PRASAD, SONAL	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/675,147	GONZALES, GILBERT R.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sonal Prasad	3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/3/04</u>   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,846,216.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the infusor system device as claimed is obvious in terms of function with the modification of a mucous membrane rather than a venous blood vessel in terms of usage, and a delivery tube rather than a venous needle in terms of delivery.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 & 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al. (5,846,216) in view of Evans et al (US 2001/0049486 A1). Claims 1 & 27 differs from Gonzales et al. in disclosing the administration of medication through venous means ([0036]). Evans et al discloses administration of medication through venous means. It would have been obvious at the time of invention to one of ordinary skill in the art to administer the medication through a venous blood vessel to improve function.

6. Claims 5-7, & 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 2001/0049486 A1) in view of Gonzales (5,846,216). Claims 5-7 differ from Evans in disclosing liquid medication, an injection site, and a valve allowing flow. ((21) & Claims 5 & 6). It would have been obvious at the time of invention to one of ordinary skill in the art to allow liquid medication through a venous blood vessel in such a manner to improve function.

7. Claims 9 & 10, and 18 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 2001/0049486 A1) in view of Gonzales (5,846,216). These claims differ from Evans in disclosing increased intrabdominal pressure ((11) & (31)). It would have been obvious at the time of invention to one of ordinary skill in the art to use an abdominal binder/restraint in such a manner to improve function.

8. Claims 16 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 2001/0049486 A1) in view of Gonzales (5,846,216). The claims differ from Evans in disclosing an IV bag with a connecting pump ((18) & (21)). It would have been obvious at the time of invention to one of ordinary skill in the art to use the IV bag and pump in such a manner to improve function.

9. Claims 24 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 2001/0049486 A1) in view of Gonzales (5,846,216). The claims differ from Evans in disclosing the spinal region of the body where the liquid medication is

delivered. ((24)). It would have been obvious at the time of invention to one of ordinary skill in the art to use the spinal region in such a manner to improve function.

10. Claims 2,3, & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al. (5,846,216) in view of Winchell et al (5,061,243). The claims differ from Gonzales in disclosing the delivery component with the venous needle and venous blood vessel and the medications (Claim 5, (48) &(4)). It would have been obvious at the time of invention to one of ordinary skill in the art to use the venous needle and medication in such a manner to improve function.

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al. (5,846,216) in view of Gordon et al. (US 2002/0188253 A1). The claims differ from Gonzales in disclosing the method of administering medication including the initiation of flow of medication and the injection site from syringe to said tube. (Claims 16,17, &20)). It would have been obvious at the time of invention to one of ordinary skill in the art to administer medication in such a manner to improve function.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

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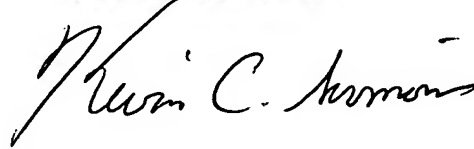
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sonal Prasad  
Examiner  
Art Unit 3767

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**KEVIN C. SIRMONS**  
**PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read "Kevin C. Sirmons", is written over the printed name and title.